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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,662	06/22/2000	Anita K. Hopper	PSU-04423	7492

7590 12/03/2001  
Thomas J. Monahan  
Intellectual Property Office  
The Pennsylvania State University  
113 Technology Center  
University Park, PA 16802-7000

EXAMINER
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DAVIS, KATHARINE F

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/03/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/599,662

Applicant(s)

HOPPER ET AL.

Examiner

Katharine F. Davis

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This Office Action is in response to the application filed on June 22, 2000 and to the Preliminary Amendment filed May 7, 2001. Claims 1-16 are pending in the instant application.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because priority to provisional applications 60/141,156 (filed June 23, 1999) and 60/199,699 (filed April 26, 2000) is improperly claimed under 35 U.S.C. 120. Priority to these provisional applications should be claimed under 35 U.S.C. 119(e).

Additionally, Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

#### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

### *Specification*

The disclosure is objected to because of the following informalities:

In the Brief Description of the Drawings each panel of a drawing containing multiple panels must be referred to as a separate figure. The first line of each description must refer to each separate figure (*e.g.*, Figures 2A-2B) Correction is required for Figures 2, 3 and 5.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pages 18 and 32). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### *Claim Objections*

Claim 1 is objected to because of the following informality: It recites the abbreviation Mod5p in line 5. It should be made clear that the "p" refers to a protein or polypeptide upon the first appearance of the abbreviation in the claims. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the instant specification claims 1-16 are drawn to assays for the

screening of compounds that are agonistic or antagonistic to the mevalonate pathway (sterol and cholesterol synthesis). However the instant claims recite only a "method" without a preamble specifically defining the use of the claimed method. Thus, the claimed method can encompass any procedure. One of skill in the art would not be able to determine the meaning of the comparisons of treated to untreated portions and thus would not be able to make and/or use the claimed methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "...Mod5p or its homolog..." It is unclear what is considered to be a homolog of Mod5p thus rendering the claim indefinite.

Claims 1, 4, 7, 10, 12 and 14 recite "...a treated portion and an untreated portion..." in (b). It is unclear if the portions are actually portions of modified yeast cells and if both treated and untreated portions are exposed to the growth media.

Claims 1, 4, 7, 10, 12 and 14 recite step "(c) measuring for growth of said treated portion." It is unclear if it is the modified yeast cells that are being measured for growth.

Claims 2, 5 and 8 recite the term "yeast cells" in line 2. There is insufficient antecedent basis for this term in the claims. This rejection may be overcome by amending the claims to recite "...**modified** yeast cells..."

Claims 3, 6, 9, 11, 13 and 15 recite a step that comprises comparing said treated portion with said untreated portion. It is unclear what property is being compared.

*Conclusion*

Claims 1-16 are rejected. Claims 1-16 are free of the prior art as the prior art does not teach or suggest assays for the screening of compounds that are agonistic or antagonistic to the mevalonate pathway. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
DAVID G. GULE  
PRIMARY EXAMINER

Katharine F. Davis  
November 30, 2001